UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 4, 2024

Journey Medical Corporation
(Exact Name of Registrant as Specified in Charter)

Delaware	**001-41063**	**47-1879539**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

9237 E Via de Ventura Blvd., Suite 105
Scottsdale, AZ 8525
(Address of principal executive offices)

Registrant's telephone number, including area code: **(480) 434-6670**

Check the appropriate box below if the Form 8-K is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:		
Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock	DERM	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02. Results of Operations and Financial Condition.

On November 4, 2024, Journey Medical Corporation ("**Journey Medical**" or the "**Company**") announced preliminary estimated unaudited revenue and selected financial results for the three- and nine-month periods ended September 30, 2024. Journey Medical's consolidated financial statements for these periods are not yet available. These estimates are based on information currently available to management. Journey Medical's actual results are not expected to vary materially from the estimated preliminary results included herein. The estimates included in this Current Report on Form 8-K have been prepared by, and are the responsibility of management, and Journey Medical's independent registered public accounting firm has not audited, reviewed, compiled, or performed any procedures with respect to the estimates and does not express an opinion or any other form of assurances with respect thereto.

Based on currently available information, Journey Medical expects to report as follows:

Three-Month Period Ended September 30, 2024

- Total net product revenues of $14.6 for the three-month period ended September 30, 2024, compared to $15.3 million for the same period in 2023.
- Gross margin of 63.9% for the three-month period ended September 30, 2024, compared to $59% for the same period in 2023.
- Research and Development ("**R&D**") expenses of $0.8 million for the three-month period ended September 30, 2024, compared to $2.2 million for the same period in 2023.

- Selling, general and administrative ("**SG&A**") expenses of $11.4 million for the three-month period ended September 30, 2024, compared to $8.6 million for the same period in 2023. Non-cash share-based compensation expense increased by $1.0 million. The remaining increase is primarily due to the expansion of the Company's access and coverage platforms and the commencement of the Company's launch efforts for Emrosi™ (Minocycline Hydrochloride Extended Release Capsules, 40 mg, formerly referred to as "DFD-29").

- Net income (loss) of $(2.4) million for three-month period ended September 30, 2024, compared to net income (loss) of $16.8 million for the three months ended September 30, 2023. The decline in net income period-over-period resulted from, in part, the $19.3 million payment made by Maruho Co., Ltd., Journey Medical's Japanese license partner ("**Maruho**"), to Journey Medical in connection with the grant by the Company of an exclusive license to Qbrexza in various Asian territories, in August of 2023 (the "**Maruho License**").

- The Company ended the third quarter of 2024 with $22.5 million in cash.

Nine-Month Period Ended September 30, 2024

- Total net product revenues of $42.5 million for the nine-month period ended September 30, 2024, compared to $44.4 million for the same period in 2023.

- R&D expense of $9.6 million for the nine-month period ended September 30, 2024, compared to $6.0 million for the same period in 2023. The increase is primarily driven by the $4.1 million filing fee payment to the U.S. Food and Drug Administration (the "**FDA**") in January 2024 for DFD-29 and $3.0 million payment for the contractual milestone payment owed to Dr. Reddy's Laboratories, Ltd ("**DRL**") triggered by the FDA's acceptance of the NDA for DFD-29 in March 2024, offset by lower clinical development expenses.

- SG&A expenses of $30.4 million for the nine-month period ended September 30, 2024, compared to $34.1 million for the same period in 2023. The decrease is due to the Company's continued expense management efforts, offset by non-cash share-based compensation, the expansion of the Company's access and coverage platforms and the commencement of the Company's launch efforts for DFD-29.

- Net income (loss) of $(16.2) million for nine-month period ended September 30, 2024, compared to net income (loss) of $(1.7) million for the nine months ended September 30, 2023. The decline in net income period-over-period resulted from, in part, the $19.3 million payment made by Maruho to Journey Medical in connection with the Maruho License.

Other Corporate Update

- *Notification of recovery of cash related to 2021 fraud loss* Pursuant to a stipulation and order signed by the Company on September 19, 2024, the United Stated District Court Southern District of New York through the United States Marshalls will be returning approximately $4.4 million of cash, recovered in connection with the previously disclosed September 2021 cybersecurity incident, to the Company. The Company expects to receive the recovered funds in the fourth quarter of 2024.

The information in this Item 2.02 of this Current Report on Form 8-K is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section. The information in this Form 8-K shall not be incorporated by reference into any filing under the Securities Act of 1933, as amended, except as shall otherwise be expressly set forth by specific reference in such filing.

Updated Financial guidance for the year ended December 31, 2024

The Company maintains its 2024 financial guidance of the following:

- Net product revenue anticipated in the range of $55-$60 million
- SG&A expense anticipated in the range of $39-$42 million
- R&D expense anticipated in the range of $9-$10 million

Item 8.01. Other Events.

On November 4, 2024, Journey Medical announced that the FDA has approved Emrosi™ (Minocycline Hydrochloride Extended Release Capsules, 40 mg), formerly referred to as DFD-29, for the treatment of inflammatory lesions of rosacea in adults. Emrosi was developed by Journey Medical in collaboration with DRL. Journey Medical is completing the manufacturing of Emrosi for the U.S. market and anticipates initial supply will be available in late first quarter or early second quarter of 2025. Journey Medical intends to commercialize Emrosi in the U.S. with its commercial team.

As previously disclosed, Journey Medical obtained global rights for the development and commercialization of Emrosi, other than in certain excluded markets, from DRL under a license, collaboration, and assignment agreement (the "**DFD-29 Agreement**"). Pursuant to the DFD-29 Agreement, the Company is contractually obligated to pay DRL contingent regulatory, commercial, and corporate-based milestone payments. The approval of Emrosi by the FDA on November 4, 2024, triggered a $15.0 million milestone payment obligation to DRL that is due 30 days after the date of the FDA's approval of the product. Additionally, the Company is required to pay royalties on net sales of Emrosi subject to certain reductions. Milestone payments made upon regulatory approval are capitalized and amortized over the remaining useful life of the related product.

Also as previously disclosed, on December 27, 2023, the Company entered into a Credit Agreement (the "**Credit Agreement**") with SWK Funding LLC ("**SWK**") that originally provided for a term loan facility in the original principal amount of up to $20.0 million. On July 9, 2024, Journey Medical entered into an amendment to the Credit Agreement with SWK that increased the original principal amount of the credit facility from $20.0 million to $25.0 million. The $5.0 million of additional principal is contractually required to be drawn on by Journey Medical upon FDA approval of DFD-29, subject to the receipt of such approval occurring on or before June 30, 2025. Accordingly, the approval of Emrosi by the FDA triggered the Company's obligation to draw on the remaining $5.0 million under the Credit Agreement. The Company intends to draw on the $5.0 million in the fourth quarter of 2024 to fund a portion of the $15 million milestone payment noted above.

On November 4, 2024, Journey Medical issued a press release announcing the FDA's approval of Emrosi a copy of which is attached hereto as Exhibit 99.1 and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The following exhibits are furnished herewith:

Exhibit Number	Description
99.1	Press release issued by Journey Medical Corporation, dated November 4, 2024.
104	Cover Page Interactive Data File, formatted in Inline Extensible Business Reporting Language (iXBRL).

Forward-Looking Statements

This Current Report on Form 8-K may contain "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. As used below and throughout this Current Report on Form 8-K, the words "the Company", "we", "us" and "our" may refer to Journey Medical. Such statements include, but are not limited to, any statements relating to our growth strategy and product development programs and any other statements that are not historical facts. The words "anticipate," "believe," "estimate," "may," "expect," "will," "could," "project," "intend," "potential" and similar expressions are generally intended to identify forward-looking statements. Forward-looking statements are based on management's current expectations and are subject to risks and uncertainties that could negatively affect our business, operating results, financial condition and stock price. Factors that could cause actual results to differ materially from those currently anticipated include: the fact that our products and product candidates are subject to time and cost intensive regulation and clinical testing and as a result, may never be successfully developed or commercialized; a substantial portion of our sales derive from products that may become subject to third-party generic competition, the introduction of new competitor products, or an increase in market share of existing competitor products, any of which could have a significant adverse impact on our operating income; we operate in a heavily regulated industry, and we cannot predict the impact that any future legislation or administrative or executive action may have on our operations; our revenue is dependent mainly upon sales of our dermatology products and any setback relating to the sale of such products could impair our operating results; competition could limit our products' commercial opportunity and profitability, including competition from manufacturers of generic versions of our products; the risk that our products do not achieve broad market acceptance, including by government and third-party payors; our reliance third parties for several aspects of our operations; our dependence on our ability to identify, develop, and acquire or in-license products and integrate them into our operations, at which we may be unsuccessful; the dependence of the success of our business, including our ability to finance our company and generate additional revenue, on the successful commercialization of our recently approved product, Emrosi™, and any future product candidates that we may develop, in-license or acquire; clinical drug development is very expensive, time consuming, and uncertain and our clinical trials may fail to adequately demonstrate the safety and efficacy of our current or any future product candidates; our competitors could develop and commercialize products similar or identical to ours; risks related to the protection of our intellectual property and our potential inability to maintain sufficient patent protection for our technology and products; our business and operations would suffer in the event of computer system failures, cyber-attacks, or deficiencies in our or our third parties' cybersecurity; the substantial doubt about our ability to continue as a going concern; the effects of major public health issues, epidemics or pandemics on our product revenues and any future clinical trials; our potential need to raise additional capital; Fortress controls a voting majority of our common stock, which could be detrimental to our other shareholders; as well as other risks described in Part I, Item 1A, "Risk Factors," in our Annual Report on Form 10-K for the year ended December 31, 2023, subsequent Reports on Form 10-Q, and our other filings we make with the SEC. We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations or any changes in events, conditions or circumstances on which any such statement is based, except as may be required by law, and we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Journey Medical Corporation
(Registrant)

By: /s/ Claude Maraoui
Claude Maraoui
Chief Executive Officer, President and Director

Date: November 4, 2024

Exhibit 99.1

Journey Medical Corporation Announces U.S. FDA Approval of Emrosi™ (Minocycline Hydrochloride Extended Release Capsules, 40 mg) for the Treatment of Rosacea

Journey Medical to host investor conference call on Monday, November 4, 2024, at 8:30 a.m. E.T.

Scottsdale, AZ – November 4, 2024 – Journey Medical Corporation (Nasdaq: DERM) ("Journey Medical"), a commercial-stage pharmaceutical company that primarily focuses on selling and marketing U.S. Food and Drug Administration ("FDA")-approved prescription pharmaceutical products for the treatment of dermatological conditions, today announced that the FDA has approved Emrosi**™** (Minocycline Hydrochloride Extended Release Capsules, 40 mg), formerly referred to as DFD-29, for the treatment of inflammatory lesions of rosacea in adults. Emrosi was developed in collaboration with Dr. Reddy's Laboratories Ltd.

Claude Maraoui, Co-Founder, President, and Chief Executive Officer of Journey Medical, said, "With approval from the FDA, Journey Medical is proud to deliver Emrosi, a unique treatment option for the millions of patients in the U.S. suffering from rosacea. Rosacea is a diffilut to treat skin condition and based on the favorable results from our Phase 3 clinical trials, Emrosi has potential to become the best-in-class oral medication to treat the condition. Our seasoned dermatology-focused sales force is now preparing for a successful launch and to establish Emrosi as a new standard of care in the treatment of rosacea. Journey Medical is committed to bringing cutting-edge innovation to patients with dermatological conditions and the healthcare professionals who treat them."

The approval of Emrosi is supported by positive data from Journey Medical's two Phase 3 clinical trials for the treatment of rosacea. The Phase 3 clinical trials met all co-primary and secondary endpoints, and subjects completed the 16-week treatment with no significant safety issues. Emrosi demonstrated statistically significant superiority over both the current standard-of-care treatment, Oracea® 40 mg capsules, and placebo for Investigator's Global Assessment treatment success as well as the reduction in total inflammatory lesion count in both studies.

Journey Medical is completing the manufacturing of Emrosi for the U.S. market and anticipates that initial supply will be available late in the first quarter or early in the second quarter of 2025. Journey Medical intends to commercialize Emrosi in the U.S. with its dermatology-focused commercial organization. In line with the approved label, Journey Medical will execute a launch strategy to drive Emrosi toward becoming a new oral standard of care for adult rosacea patients.

Srinivas Sidgiddi, M.D., Vice President, Research & Development at Journey Medical, added, "Emrosi showed great efficacy and tolerability in the pivotal clinical trials, and we are tremendously grateful to the patients, physicians, investigators, and site coordinators who participated and contributed to this important approval milestone."

Conference Call and Replay Information
Journey Medical management will host a conference call to review the FDA approval on Monday, November 4, 2024, at 8:30 a.m. Eastern Time.

To listen to the conference call, interested parties within the U.S. should dial 1-866-777-2509 (domestic) or 1-412-317-5413 for international callers. All callers should dial in approximately 10 minutes prior to the scheduled start time and ask to be joined into the Journey Medical conference call. Participants can register for the conference call online by clicking the following link: https://dpregister.com/sreg/10193869/fdcd4e50be. Please note that registered participants will receive their dial-in number upon registration.

A replay of the conference call will be available shortly after the call concludes for approximately two weeks, and can be accessed by dialing 1-877-344-7529 (domestic) or 1-412-317-0088 (international), and providing the replay access code: 8833884. Participants will be required to state their name and company upon registering for the replay.

Important Safety Information

Indication: EMROSI™ is indicated for the treatment of inflammatory lesions (papules and pustules) of rosacea in adults. Adverse Events: The most common adverse reaction reported by ≥1% of subjects treated with EMROSI and more frequently than in subjects receiving placebo was dyspepsia. Contraindications: EMROSI should not be taken by patients who have a history of hypersensitivity to any of the tetracyclines. Warnings/Precautions: Cases of anaphylaxis, serious skin reactions (e.g., Stevens-Johnson syndrome), erythema multiforme, and drug rash with eosinophilia and systemic symptoms (DRESS) syndrome have been reported postmarketing with minocycline use in patients with acne. If DRESS syndrome is recognized, discontinue EMROSI immediately. Use during the second and third trimesters of pregnancy, infancy and childhood up to the age of 8 years may cause permanent discoloration of the teeth and reversible inhibition of bone growth. Discontinue EMROSI use if Antibiotic-Associated Colitis occurs. Discontinue EMROSI if liver injury is suspected. Patients experiencing light-headedness, dizziness or vertigo should be cautioned about driving vehicles or operating heavy machinery. Clinical manifestations include headache, blurred vision, diplopia, and vision loss. Discontinue EMROSI immediately if symptoms occur. Symptoms may be manifested by fever, rash, arthralgia, and malaise. Discontinue EMROSI immediately if symptoms occur. Patients should minimize or avoid exposure to natural or artificial sunlight while using EMROSI. Tetracycline-class antibiotics are known to cause hyperpigmentation. EMROSI may induce hyperpigmentation in many organs, including nails, bone, skin, eyes, thyroid, visceral tissue, oral cavity, sclerae and heart valves. Because of the potential for drug-resistant bacteria to develop during the use of EMROSI, use EMROSI only as indicated. If superinfection occurs, discontinue EMROSI and institute appropriate therapy. Perform periodic laboratory evaluations of organ systems, including hematopoietic, renal and hepatic studies. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

For full prescribing information, please visitwww.emrosi.com.

About Rosacea
Rosacea is a chronic, relapsing, inflammatory skin condition that most commonly presents with symptoms such as deep facial redness, acne-like inflammatory lesions (papules and pustules) and spider veins (telangiectasia). According to The National Rosacea Society, it is estimated that rosacea affects well over 16 million Americans and as many as 415 million people worldwide. Rosacea is most frequently seen in adults between 30 and 50 years of age. Surveys conducted by The National Rosacea Society report that more than 90 percent of rosacea patients said their condition had lowered their self-confidence and self-esteem, and 41 percent stated that it had caused them to avoid public contact or cancel social engagements. Among rosacea patients with severe symptoms, 88 percent said the disorder had adversely affected their professional interactions, and 51 percent said they had missed work because of their condition.

About Journey Medical Corporation

Journey Medical Corporation (Nasdaq: DERM) ("Journey Medical") is a commercial-stage pharmaceutical company that primarily focuses on the selling and marketing of FDA-approved prescription pharmaceutical products for the treatment of dermatological conditions through its efficient sales and marketing model. The Company currently markets seven branded and two generic products that help treat and heal common skin conditions. The Journey Medical team comprises industry experts with extensive experience in developing and commercializing some of dermatology's most successful prescription brands. Journey Medical is located in Scottsdale, Arizona and was founded by Fortress Biotech, Inc. (Nasdaq: FBIO). Journey Medical's common stock is registered under the Securities Exchange Act of 1934, as amended, and it files periodic reports with the U.S. Securities and Exchange Commission ("SEC"). For additional information about Journey Medical, visit www.journeymedicalcorp.com.

Forward-Looking Statements

This press release may contain "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. As used below and throughout this press release, the words "the Company", "we", "us" and "our" may refer to Journey Medical. Such statements include, but are not limited to, any statements relating to our growth strategy and product development programs and any other statements that are not historical facts. The words "anticipate," "believe," "estimate," "may," "expect," "will," "could," "project," "intend," "potential" and similar expressions are generally intended to identify forward-looking statements. Forward-looking statements are based on management's current expectations and are subject to risks and uncertainties that could negatively affect our business, operating results, financial condition and stock price. Factors that could cause actual results to differ materially from those currently anticipated include: the fact that our products and product candidates are subject to time and cost intensive regulation and clinical testing and as a result, may never be successfully developed or commercialized; a substantial portion of our sales derive from products that may become subject to third-party generic competition, the introduction of new competitor products, or an increase in market share of existing competitor products, any of which could have a significant adverse impact on our operating income; we operate in a heavily regulated industry, and we cannot predict the impact that any future legislation or administrative or executive action may have on our operations; our revenue is dependent mainly upon sales of our dermatology products and any setback relating to the sale of such products could impair our operating results; competition could limit our products' commercial opportunity and profitability, including competition from manufacturers of generic versions of our products; the risk that our products do not achieve broad market acceptance, including by government and third-party payors; our reliance third parties for several aspects of our operations; our dependence on our ability to identify, develop, and acquire or in-license products and integrate them into our operations, at which we may be unsuccessful; the dependence of the success of our business, including our ability to finance our company and generate additional revenue, on the successful commercialization of our recently approved product, Emrosi™, and any future product candidates that we may develop, in-license or acquire; clinical drug development is very expensive, time consuming, and uncertain and our clinical trials may fail to adequately demonstrate the safety and efficacy of our current or any future product candidates; our competitors could develop and commercialize products similar or identical to ours; risks related to the protection of our intellectual property and our potential inability to maintain sufficient patent protection for our technology and products; our business and operations would suffer in the event of computer system failures, cyber-attacks, or deficiencies in our or our third parties' cybersecurity; the substantial doubt about our ability to continue as a going concern; the effects of major public health issues, epidemics or pandemics on our product revenues and any future clinical trials; our potential need to raise additional capital; Fortress controls a voting majority of our common stock, which could be detrimental to our other shareholders; as well as other risks described in Part I, Item 1A, "Risk Factors," in our Annual Report on Form 10-K for the year ended December 31, 2023, subsequent Reports on Form 10-Q, and our other filings we make with the SEC. We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations or any changes in events, conditions or circumstances on which any such statement is based, except as may be required by law, and we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

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